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Attorney Docket No. P58126US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of Metin COLPAN

Application No.: 08/796,040

Art Unit: 1623

Filed: February 5, 1997

Examiner: Lawrence E. Crane

For: DEVICE AND A PROCESS FOR THE ISOLATION OF NUCLEIC ACID

REPLY BRIEF

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

P58126US1 Text insert #1

The instant brief is submitted in reply to the Examiner's Answer mailed March 13, 2007 (hereafter, the "Answer").

Claims 120-138, as set forth the Claims Appendix of the substitute reply brief filed December 4, 2006 (hereafter, the "appeal brief"), are subject to final rejection—maintained in the Answer—under 35 USC 103(a) as being allegedly unpatentable over US 5,057,426 (Henco), in view of US 5,075,430 (Little) and, further, in view of *International Dictionary of Medicine and Biology, I*, 1986, page 522 (*International Dictionary*), and *Nucleic Acid Hybridisation - A Practical Approach*, 1985, pages 64, 65, and 235 (Hames).

Answer does not respond to appeal brief of record

The appeal brief of record was filed December 4, 2006, pursuant to the Order mailed June 29, 2006, and in response to the Notification of Non-Compliant Appeal Brief, mailed August 24,

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2006. However, at page 2, line 1, of the Answer the examiner states "This is in response to the appeal brief filed June 10, 2005."

Moreover, the Answer cites specific pages (and paragraphs) when referring to passages in the appeal brief, which pages do not contain the passages referred to, i.e, specifically:

- citations to "page 6" of the appeal brief (Answer, pages 7 and 8).
- citations to "page 8" of the appeal brief (Answer, page 8).
- citations to "page 9" of the appeal brief (Answer, page 9).
- citation to "page 10" of the appeal brief (Answer, page 9).
- citations to "page 11" of the appeal brief (Answer, page 9).
- citations to "page 12" of the appeal brief (Answer, page 10).
- citation to "page 13" of the appeal brief (Answer, page 11).
- citation to "page 14 and . . . page 15" of the appeal brief (Answer, page 11).
- citations to "page 19" of the appeal brief (Answer, page 12).
- citation to "page 22 and . . . page 23" of the appeal brief (Answer, page 12).
- citation to "22 and . . . pages 24-26" of the appeal brief (Answer, page 12).

Allegations directed against "Summary of Invention" are erroneous

According to the Answer (page 2, final paragraph) the brief on appeal is "deficient" because there are three "advantages" set forth in the summary of invention, which are allegedly not included in the claims. In that these are "advantages" of the presently claimed invention—as alleged/admitted in the Answer—they need not be recited in the claims. When the record establishes that "advantages

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accrue from the claimed process . . . it is not required that they be recited [in the claims]." *In re Estes*, 1764 USPQ 519, 521 (CCPA 1970). Failure "to consider the results achieved by Appellant because they are not recited in the claims is legally "incorrect." *Estes*, 164 USPQ at 521.

As set forth in the paragraph bridging pages 8 and 9 of the subject application (see the paragraph bridging pages 8 and 9 of the appeal brief),

Surprisingly the process according to the invention shows . . . a combination of anion exchanger and silica gel . . . wherein the anion exchanger serves to purify the nucleic acid, and while at concentrations of from 0.25 to 1.5 M of salt, impurities such as metabolites, proteins and impart, RNA, and polysaccharides are removed, these are not capable of adsorbing to the downstream silica gel layer under the conditions given, and the silica gel layer serves the object of desalting and concentrating, when the nucleic acid in the following step is eluted from the anion exchanger at a salt concentration sufficiently high to enable nucleic acid adsorption to the silica gel layer.

Since the record, i.e., the aforesaid unrebutted teachings of the presently claimed invention, "these advantages accrue from the claimed process, and it is not required that they be recited [in the claims]." *Estes*, 164 USPQ at 521.

Moreover, the first two advantages (allegedly absent from the claims) are, in fact, found in the claims. According to the Answer the first two advantages are:

First, all of the claims are not limited to a directly tandem linkage between the first two steps in the first and fourth steps as required at the end of the first paragraph of Appellant's "Summary." Secondly, in the fourth paragraph of Appellant's "Summary" the advantage of a single buffer being usable for two separate steps is not specifically included as a claim limitation.

Both of these allegedly missing limitations are, in fact, found in the claims on appeal.

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Claim 120 (appeal brief, Claims Appendix) (emphasis added) recites steps "b)" and "c)" in "first" and "second" stages, respectively:

b) desorbing the nucleic acids from the anion exchanger by applying a second buffer solution . . . effecting purified nucleic acids in the second buffer solution; and . . .

c) absorbing the separation/purified nucleic acids in the second buffer solution onto the surface of a mineral support material.

Accordingly, step "c)" uses "the [same] second buffer solution" used in first-stage-desorbing step "b)," i.e., by "adsorbing the separation/purified nucleic acids in the second buffer solution"—effected in the immediately preceding step b)—onto the surface of a mineral support material."

Contrary to the allegations in the Answer, the "second buffer solution" recited in the claims is "a single buffer . . . usable for two separate steps . . . specifically included as a claim limitation." Moreover, the first allegedly missing claim limitation (the first and second stages being operated in tandem) is found in the claims by virtue of second advantage being present.

As set forth in the invention summary of the appeal brief (page 7, first paragraph) (emphasis added), there are

two chromatographic purification (adsorbing-desorbing) stages, operated in tandem; whereby, purified nucleic-acid-containing material obtained in the first stage is applied to the second stage, directly, as it comes from the first stage.

As explained above, the same "purified nucleic acids in the second buffer solution"—obtained in first-stage step b)—are adsorbed—in second-stage step c)—"onto the surface of a mineral support material."

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This tandem, i.e., sequential, arrangement—wherein step c) directly follows step b)—is not a mere arbitrary arrangement. As explained at page 8, last incomplete paragraph, of the appeal brief: "The presently claimed process provides unique advantages . . . in the recited tandem *order* of using . . . the exchange material, first, followed by the mineral support."

Answer incorrectly alleges that no "reasons" supporting "statement" are provided

The Answer (page 3, under the heading "Grouping of Claims"), incorrectly alleges that the substitute brief "fails to present reasons" for the "statement that claims 120-138 do not stand or fall together." The allegedly missing "reasons" are found at pages 29-30 of the Brief, following the heading "(B) Claims 122-126 and 129-136."

Answer's reducing the claimed invention to a gist or core is legally erroneous

According to the Answer (page 6, first incomplete paragraph) the rejection under §103(a) relies on the alleged

lack [of] an adequate basis for finding of patentable distinction for any variation of the instant claimed process, as such variations are deemed to have been properly included within the scope of the noted prior art.

Therefore, the instant claimed process for DNA purification by anion exchange chromatography followed by desalting using an entirely conventional adsorption chromatographic process would have been obvious to one of ordinary skill in the art.

As explained in the appeal brief (pages 29-30) reliance on claim limitations "deemed" to be found in the prior art renders the rejection of claim 122-126 and 129-136 non-sustainable. Therefore, characterizing "the instant claimed process" as "DNA purification by anion exchange chromatography followed by desalting using an entirely conventional adsorption chromatographic

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process" effectively discards, *i.e.*, the "deemed" limitations. Since the examiner effectively "disregarded express claim limitations" in order to reject the claims under §103(a), the presently claimed invention was erroneously reduced to a "gist or core" in order to support the rejection. *Bausch & Lomb v. Barnes-Hind/Hydrocurve*, 230 USPQ 416, 420 (Fed. Cir. 1986).

Answer erroneously concludes that appeal brief applies anticipation test

At page 8 of the Answer, the Examiner alleges "Appellant appears to be applying an anticipation test" with respect to arguments found in Appellant's Substitute Brief (the identification of these arguments being found on "page 8 of the Brief" is a mistake in the Answer as discussed below). Contrary to the Examiner's allegations, Appellant is not applying an anticipation test; but, on the contrary, properly demonstrating lack of obviousness, under §103(a) by showing that "individual defects of the reference . . . can defeat the rejection" based on its combination with another reference, under §103(a). *In re Lyons*, 150 USPQ 741, 746 (CCPA 1966).

Answer erroneously finds teachings of invention include background teachings

At page 9, second complete paragraph, of the Answer, the examiner improperly combines disclosure found in the background of the invention of Little with the invention disclosure of Little, *i.e.*, in alleging that the aforesaid teachings are disclosed in Little. This renders the rejection legally erroneous since a patentee's acknowledgments of the state of the art [in the background of invention] are "not . . . an enlargement of the invention described in the patent" and "would not be so understood by a person skilled in the field of the invention." *Wang Laboratories Inc. v. America Online, Inc.*, 53 USPQ2d 1161, 1164 (Fed. Cir. 1999).

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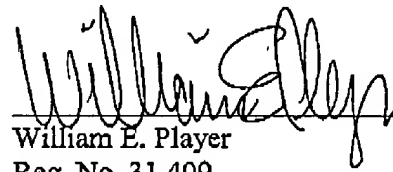
CONCLUSION

For the foregoing reasons, taken in conjunction with those set forth in the appeal brief, reversal of all appealed rejections of record is requested.

Respectfully submitted,

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